K130398

510(k) SUMMARY

Submitted By:	Quidel Corporation 10165 McKellar Court San Diego, California 92121 Telephone: 858-552-7908 Fax: 858-646-8045
Submission Contact:	John D. Tamerius, Ph.D.
Date Prepared:	February 15, 2013
Device Trade Name:	Sofia® RSV FIA
Common Name:	Respiratory Syncytial Virus (RSV) Test
Predicate Device:	BD Veritor™ System for Rapid Detection of RSV, K121633
Device Classification/Name:	21 CFR 866.3480 / Respiratory syncytial virus serological reagents These tests are used to aid in the diagnosis of disease caused by respiratory syncytial viruses and provide epidemiological information on these diseases (21 CFR 866.3480). The Food and Drug Administration has classified serological test systems for the detection of respiratory syncytial virus as Class I.
Intended Use:	The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.

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Physiologic Basis of the Test:

RSV is a causative agent of highly contagious, acute, viral infection of the respiratory tract in pediatric and elderly populations. Respiratory syncytial virus is a single-stranded RNA virus. Nearly half of all children become infected by RSV in their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. In the United States, RSV is estimated to be responsible for 73,400 to 126,300 hospitalizations annually for bronchiolitis and pneumonia alone among children younger than 1 year. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. Among children hospitalized with RSV infection, the mortality rate is estimated to be as low as 0.3% to 1.0% and in the range of 2.5% to 4.0% for children with underlying cardiac or pulmonary disease.

Device Description:

The Sofia RSV FIA test employs immunofluorescence technology that is used with the Sofia Analyzer for the rapid detection of RSV antigens. The Sofia RSV FIA test involves the disruption of RSV viral antigens. The patient specimen is placed in the Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After disruption, the specimen is dispensed into the Cassette sample well. From the sample well, the specimen migrates through a test strip containing various unique chemical environments. If RSV viral antigens are present, they will be trapped in a specific location.

> **Note:** Depending upon the user's choice, the cassette is either placed inside of the Sofia Analyzer for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into the Sofia Analyzer to be scanned (Read Now Mode).

The Sofia Analyzer will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. The Sofia Analyzer will display the test results (Positive, Negative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected.

Device Comparison:

Item	Proposed Device	Predicate Device
Features	**Sofia RSV FIA**	**BD Veritor™ System for Rapid Detection of RSV, K121633**
Intended Use	The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.	The BD Veritor System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media samples from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor System Reader.
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen
Instrument	Sofia Analyzer	BD Veritor
Calibrator	Yes; a Calibration Cassette and QC Card are provided	No calibrator; a verification device is provided to monitor device function
Specimen Types	Nasopharyngeal swab and nasopharyngeal aspirate/wash specimens; all specimens can be tested fresh or after transport in media	Nasopharyngeal swab in transport media and nasopharyngeal aspirate/wash specimens
Read Result Time	15 Minutes	Approximately 10 Minutes

Item	Proposed Device	Predicate Device
Features	**Sofia RSV FIA**	**BD Veritor™ System for Rapid Detection of RSV, K121633**
External Controls	RSV positive swab RSV negative swab	RSV positive swab RSV negative swab

Summary of Performance Data:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. These studies included the following:

1. A multi-center field clinical study was undertaken to document the performance characteristics of the test. Sensitivity and specificity were calculated using nasopharyngeal swab and nasopharyngeal aspirate/wash specimens, both fresh and after storage in transport media.
2. A reproducibility study was performed to demonstrate intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various RSV concentrations.
3. Analytical studies included Limit of Detection, analytical reactivity, cross reactivity, interfering substances, operating temperature, lab precision/repeatability, viral transport media, inter-analyzer variation assessment, calibration cycle, and various flex studies.

Conclusion:

These studies demonstrated the substantial equivalence of the Sofia RSV FIA for use with the Sofia Analyzer to the existing product already marketed, BD Veritor System for Rapid Detection of RSV, K121633. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2013

JOHN D. TAMERIUS
SENIOR VICE PRESIDENT, CLINICAL AND REGULATORY AFFAIRS
QUIDEL CORPORATION
10165MCKELLAR COURT
SAN DIEGO CA 92121

Re: K130398
Trade/Device Name: Sofia® RSV FIA
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: I
Product Code: GQG
Dated: June 28, 2013
Received: July 1, 2013

Dear Dr. Tamerius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, Ph.D., M.Sc
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130398

Device Name: Sofia® RSV FIA

Indications For Use:

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)